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Atty Docket No.: JHV-050.01

Filing Date: May 5, 2004

Inventor: Tzyy-Choou Wu et al.

ANTI-CANCER DNA VACCINE EMPLOYING PLASMIDS ENCODING SIGNAL ANTI-CANCER UNA VACCINE EMPLOTING PLASMIUS ENCUCING SIGNAL SEQUENCE, MUTANT ONCO-PROTEIN ANTIGEN, AND HEAT SHOCK PROTEIN Application No.:

Response to Notification of Missing Requirements (2 pages in dupl.) Documents Filed:

Copy of Notification of Missing Requirements (3 pages) Petition for Four Month Extension of Time Under 37 CFR 1.136(a) (1 page in dupl.)

Paper copy of Sequence Listing (17 pages) CRF diskette of Sequence Listing (1 disk)

Statement to Suppport Sequence Listing submission (1 page)

Preliminary Amendment (3 pages)

Executed Declaration (1 page) Executed Powers of Attorney (2 pages)

Notification of Change of Attorney Docket Number (1 page) MAR 2 9 2007

Via: First Class Mail JYA/dmn Sender's Initials:

DOCKETING

RECEIVED

IAP6 Rec'd PCT/PTO 22 MAR 2007

Inventor: Tzyy-Choou Wu et al.

Atty Docket No.: JHV-050.01

Application No.:

10/555,669-Conf. #9879

Filing Date: May 5, 2004 ANTI-CANCER DNA VACCINE EMPLOYING PLASMIDS ENCODING SIGNAL SEQUENCE, MUTANT ONCO-PROTEIN ANTIGEN. AND HEAT SHOCK PROTEIN

Documents Filed:

Response to Notification of Missing Requirements (2 pages in dupl.)

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Via: First Class Mail

Sender's Initials: JYA/dmn

Date: March 19, 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Wu, Tzyy-Choou et al.

Application No: 10/555,669

International Filing Date: May 5, 2004

FOI: ANTI-CANCER DNA VACCINE EMPLOYING PLASMIDS ENCODING SIGNAL SEQUENCE, MUTANT ONCO-PROTEIN ANTIGEN, AND HEAT

SHOCK PROTEIN

Art Unit: To be Determined

Confirmation No.: 9879

Examiner: To be Determined

Docket No. JHV-050.01

CERTIFICATE OF FIRST CLASS MAILING

I hereby certify that the foregoing documents are being deposited with the United States Postal Service as First Class Mail, in an envelope addressed to Mail Stop PCT (DO/BO/US), Commissioner 100 Datents, P.O. Box 1450, Alexandria VA 22313-1450, on this date of March 19, 2007.

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS

Mail Stop PCT (DO/EO/US) Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This paper is being filed in response to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) mailed on September 19, 2006, in the above-referenced application.

Enclosed is a copy of the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US); a Petition for a Four-Month Extension of Time; a paper copy of the Sequence Listing; a Computer Readable Form of the Sequence Listing (CRF); a Statement to Support the Filing and Submission of the Sequence Listing in accordance with 37 CFR §§1.821-1.825; a Preliminary Amendment; Declaration signed by Inventors Wu and Hung; and Powers of Attorney signed by Inventors Wu and Hung.

Please charge the surcharge for a small entity (\$65.00) to our Deposit Account No. 06-1448, Reference JHV-050.01. A copy of this Response is enclosed. Although we believe that we have submitted the correct amount to cover the above-listed items, the Commissioner is authorized to credit any overpayment or charge any deficiencies to our Deposit Account No. 06-1448, Reference JHV-050.01.

Respectfully Submitted,

anann al:

Date: March 19, 2007

Customer No: 25181
Patent Group
Foley Hoag LLP
155 Seaport Blvd.
Boston, MA 02210-2600

Janam Y. Ali, Ph.D. Reg. No. 54,958 Agent for Applicants Tel. (617) 832-1000 Fax. (617) 832-7000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Wu, Tzyy-Choou et al.

Application No: 10/555,669

International Filing Date: May 5, 2004

For: ANTI-CANCER DNA VACCINE EMPLOYING PLASMIDS ENCODING

> SIGNAL SEQUENCE, MUTANT ONCO-PROTEIN ANTIGEN, AND HEAT

SHOCK PROTEIN

Art Unit: To be Determined

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Date: March 19, 2007

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Patent Group
Foley Hoag LLP
155 Seaport Blvd.
Boston, MA 02210-2600

Janann Y. Ali, Ph.D.

Reg. No. 54,958 Agent for Applicants Tel. (617) 832-1000 Fax. (617) 832-7000



JHU-18

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS PO Rev 1450

Page 1 of 3

U.S. APPLICATION NUMBER NO. FIRST NAMED APPLICANT ATTV. DOCKET NO.

10/555,669 Tzyy-Choou Wu INTERNATIONAL APPLICATION NO.

PCT/USQ4/13756

Missing Requirement LA FILING DAT DUE: 1/19/07-w/2 moca + 05/05/2004

LA. FILING DATE PRIORITY DATE

∠ 05/05/2004 05/05/2003

DUE: 111910 FINAL - 4/1910

CONFIRMATION NO. 9879

371 FORMALITIES LETTER

OC00000020495147

Date Mailed: 09/19/2006

McKenna Long & Aldridge

1900 K Street NW Washington, DC 20006

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- · Indication of Small Entity Status
- . Copy of the International Application filed on 11/07/2005
- Copy of the International Search Report filed on 11/07/2005
- Preliminary Amendments filed on 11/07/2005
- Information Disclosure Statements filed on 11/07/2005
- U.S. Basic National Fees filed on 11/07/2005
- Priority Documents filed on 11/07/2005



The applicant needs to satisfy supplemental fees problems indicated below.

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application
 by the International application number and international filling date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath
 or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27,
 must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$65 for a Small Entity:

\$65 Surcharge.

- This application clearly fails to comply with the requirements of 37 CFR. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment specifically directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825 (d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821 (e) may be submitted in lieu of a new CRF.
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice MUST be returned with the response.

JOHN L ANDERSON

Telephone: (703) 308-9140 EXT 211

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/555 660	DCT/IS04/12756	26148,1180

10/555,669

PCT/US04/13756

FORM PCT/DO/EO/905 (371 Formalities Notice)

Approved for use through 03/31/2007. OMB 0551-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless if displays a valid OMB control Docket Number (Optional) PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2006 JHV-050.01 (Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).) Application Number 10/555.669-Conf. #9879 Filed May 5, 2004 ANTI-CANCER DNA VACCINE EMPLOYING PLASMIDS ENCODING SIGNAL SEQUENCE MUTANT ONCO-PROTEIN ANTIGEN. AND HEAT SHOCK PROTEIN Art Unit Examiner Not Yet Assigned This is a request under the provisions of 37 CFR 1,136(a) to extend the period for filing a reply in the above identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below): Fee Small Entity Fee One month (37 CFR 1.17(a)(1)) \$120 \$60 Two months (37 CFR 1.17(a)(2)) \$450 \$225 Three months (37 CFR 1.17(a)(3)) \$1020 \$510 Four months (37 CFR 1.17(a)(4)) \$1590 \$795 795.00 Five months (37 CFR 1.17(a)(5)) \$2160 \$1080 Applicant claims small entity status. See 37 CFR 1.27. A check in the amount of the fee is enclosed. Payment by credit card. Form PTO-2038 is attached. The Director has already been authorized to charge fees in this application to a Deposit Account. The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number Ref: JHV-050.01 . I have enclosed a duplicate copy of this sheet. I am the applicant/inventor. assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96). attorney or agent of record. Registration Number 54,958 attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 anann (March 19, 2007 Date Janann Y. Ali (617) 832-1000 Telephone Number Typed or printed name NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

I hereby certify that this pape the date shown below with su Patents, P.O. Box 1450, Alex	(along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on filicient postage as First Class Mall, in an employs of the second to: Mall Stop PCT (DO/EO/US), Commissioner for andria, VA 2313-1450.
Dated: March 19, 2007	Signature:(John Barretto)

forms are submitted.

х Total of 2

U.S. Patent and Trademark Office; U.S. Detail of the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless if displays a valid CMB control number. Docket Number (Optional) PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2006 JHV-050.01 (Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).) May 5, 2004 Filed Application Number 10/555,669-Conf. #9879 ANTI-CANCER DNA VACCINE EMPLOYING PLASMIDS ENCODING SIGNAL SEQUENCE, MUTANT For ONCO-PROTEIN ANTIGEN, AND HEAT SHOCK PROTEIN Not Yet Assigned Examiner Art Unit This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below): Small Entity Fee Fee \$120 \$60 One month (37 CFR 1.17(a)(1)) \$450 \$225 Two months (37 CFR 1.17(a)(2)) \$510 Three months (37 CFR 1.17(a)(3)) \$1020 \$795 795.00 Four months (37 CFR 1.17(a)(4)) \$1590 \$2160 \$1080 Five months (37 CFR 1.17(a)(5)) X Applicant claims small entity status. See 37 CFR 1.27. A check in the amount of the fee is enclosed. Payment by credit card. Form PTO-2038 is attached. The Director has already been authorized to charge fees in this application to a Deposit Account. X | The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to 06-1448. Deposit Account Number Ref: JHV-050.01 I have enclosed a duplicate copy of this sheet. I am the applicant/inventor. assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96). attorney or agent of record. Registration Number 54,958 attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 Ianann a March 19, 2007 Signature Date (617) 832-1000 Janann Y. Ali Telephone Number Typed or printed name NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

hereby certify that this paper (along with any paper referred to as being attached or processed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as Feist Class Mall, in an empirity of processed for Mall Step PCT (DOEONUS), Commissioner for Paterias, P.O., Sox 1450, Alexandria, V.S. 22313-1450.
Dated: March 19, 2007 Signature:(John Barretto)

forms are submitted.

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Total of

2



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket No: JHV-050.01 (19546-5001)

In re patent application of

WU. TZZY-CHOOU et al.

Serial No. 10/555,669

Filed: May 5, 2004

For: ANTI-CANCER DNA VACCINE EMPLOYING PLASMIDS ENCODING SIGNAL SEQUENCE, MUTANT ONCOPROTEIN ANTIGEN, AND HEAT SHOCK PROTEIN

STATEMENT TO SUPPORT FILING AND SUBMISSION IN ACCORDANCE WITH 37 C.F.R. §§ 1.821-1.825

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Mail Stop SEQUENCE

Sir:

In connection with a Sequence Listing submitted concurrently herewith, the undersigned hereby states that:

- 1. the submission, filed herewith in accordance with 37 C.F.R. § 1.821(g), does not include new matter;
- the content of the attached paper copy and the attached computer readable copy of the Sequence Listing, submitted in accordance with 37 C.F.R. § 1.821(c) and (e), respectively, are the same.

Respectfully submitted,

reb. 15, 20

HARBOR CONSULTING IP SERVICES, INC. 1500A Lafayette Road, #262 Portsmouth, N.H. 03801 800-318-3021

SECUENCE LISTING

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	HIM	3	CHIEN	FII

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<211> 625 <212> PRT

<213> Mycobacterium tuberculosis

<400> 10

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Ser Val Leu Glu Gly Gly Asp Pro Val Val Val Ala Asn Ser Glu Gly

Ser Arg Thr Thr Pro Ser Ile Val Ala Phe Ala Arg Asn Gly Glu Val 35 40 45

Leu Val Gly Gln Pro Ala Lys Asn Gln Ala Val Thr Asn Val Asp Arg 50 55 60

Thr Val Arg Ser Val Lys Arg His Met Gly Ser Asp Trp Ser Ile Glu 65 70 75 80

Ile Asp Gly Lys Lys Tyr Thr Ala Pro Glu Ile Ser Ala Arg Ile Leu 85 90 95

Met Lys Leu Lys Arg Asp Ala Glu Ala Tyr Leu Gly Glu Asp Ile Thr 100 105 110

Asp Ala Val Ile Thr Thr Pro Ala Tyr Phe Asn Asp Ala Gln Arg Gln 115 120 125

Ala Thr Lys Asp Ala Gly Gln Ile Ala Gly Leu Asn Val Leu Arg Ile 130 135 140

Val Asn Glu Pro Thr Ala Ala Ala Leu Ala Tyr Gly Leu Asp Lys Gly 145 150 150 160

Glu Lys Glu Gln Arg Ile Leu Val Phe Asp Leu Gly Gly Gly Thr Phe 165 \$170\$

Asp Val Ser Leu Leu Glu Ile Gly Glu Gly Val Val Glu Val Arg Ala 180 \$180\$

Thr Ser Gly Asp Asn His Leu Gly Gly Asp Asp Trp Asp Gln Arg Val

Val Asp Trp Leu Val Asp Lys Phe Lys Gly Thr Ser Gly Ile Asp Leu 210 215 220

Thr Lys Asp Lys Met Ala Met Gln Arg Leu Arg Glu Ala Ala Glu Lys 225 230235235

Ala Lys Ile Glu Leu Ser Ser Ser Gln Ser Thr Ser Ile Asn Leu Pro \$245\$

Tyr Ile Thr Val Asp Ala Asp Lys Asn Pro Leu Phe Leu Asp Glu Gln 260 265 270

7 Leu Thr Arg Ala Glu Phe Gln Arg Ile Thr Gln Asp Leu Leu Asp Arg 280 285 275 Thr Arg Lys Pro Phe Gln Ser Val Ile Ala Asp Thr Gly Ile Ser Val Ser Glu Ile Asp His Val Val Leu Val Gly Gly Ser Thr Arg Met Pro Ala Val Thr Asp Leu Val Lys Glu Leu Thr Gly Gly Lys Glu Pro Asn Lys Gly Val Asn Pro Asp Glu Val Val Ala Val Gly Ala Ala Leu Gln Ala Gly Val Leu Lys Gly Glu Val Lys Asp Val Leu Leu Leu Asp Val Thr Pro Leu Ser Leu Gly Ile Glu Thr Lys Gly Gly Val Met Thr Arg Leu Ile Glu Arg Asn Thr Thr Ile Pro Thr Lys Arg Ser Glu Thr Phe Thr Thr Ala Asp Asp Asn Gln Pro Ser Val Gln Ile Gln Val Tyr Gln 410 Gly Glu Arg Glu Ile Ala Ala His Asn Lys Leu Leu Gly Ser Phe Glu 425 Leu Thr Gly Ile Pro Pro Ala Pro Arg Gly Ile Pro Gln Ile Glu Val Thr Phe Asp Ile Asp Ala Asn Gly Ile Val His Val Thr Ala Lys Asp Lys Gly Thr Gly Lys Glu Asn Thr Ile Arg Ile Gln Glu Gly Ser Gly Leu Ser Lys Glu Asp Ile Asp Arg Met Ile Lys Asp Ala Glu Ala His Ala Glu Glu Asp Arg Lys Arg Arg Glu Glu Ala Asp Val Arg Asn Gln Ala Glu Thr Leu Val Tyr Gln Thr. Glu Lys Phe Val Lys Glu Gln Arg Glu Ala Glu Gly Gly Ser Lys Val Pro Glu Asp Thr Leu Asn Lys Val 535

Asp Ala Ala Val Ala Glu Ala Lys Ala Ala Leu Gly Gly Ser Asp Ile 545 550 Ser Ala Ile Lys Ser Ala Met Glu Lys Leu Gly Gln Glu Ser Gln Ala 565 570

Leu Gly Gln Ala Ile Tyr Glu Ala Ala Gln Ala Ala Ser Gln Ala Thr 585 580 Gly Ala Ala His Pro Gly Gly Glu Pro Gly Gly Ala His Pro Gly Ser 600 Ala Asp Asp Val Val Asp Ala Glu Val Val Asp Asp Gly Arg Glu Ala 615 Lys 625 <210> 11 <211> 2104 <212> DNA <213> Artificial Sequence <220> <221> CDS <222> (1)..(2103) -220> <223> Description of Artificial Sequence: Synthetic construct <400> 11 atg cat gga gat aca cct aca ttg cat gaa tat atg tta gat ttg caa Met His Gly Asp Thr Pro Thr Leu His Glu Tyr Met Leu Asp Leu Gln cca gag aca act gat etc tac tgt tat gag caa tta aat gac age tca Pro Glu Thr Thr Asp Leu Tyr Cys Tyr Glu Gln Leu Asn Asp Ser Ser qaq qaq qat qaa ata qat ggt cca gct gga caa gca gaa ccg gac Glu Glu Glu Asp Glu Ile Asp Gly Pro Ala Gly Gln Ala Glu Pro Asp aga gcc cat tac aat att gta acc ttt tgt tgc aag tgt gac tct acg Arg Ala His Tyr Asn Ile Val Thr Phe Cys Cys Lys Cys Asp Ser Thr ctt cgg ttg tgc gta caa agc aca cac gta gac att cgt act ttg gaa Leu Arg Leu Cys Val Gln Ser Thr His Val Asp Ile Arg Thr Leu Glu gac etg tta atg gge aca eta gga att gtg tge eec ate tgt tet caa Asp Leu Leu Met Gly Thr Leu Gly Ile Val Cys Pro Ile Cys Ser Gln gga tee atg get egt geg gte ggg ate gae ete ggg ace ace aac tee Gly Ser Met Ala Arg Ala Val Gly Ile Asp Leu Gly Thr Thr Asn Ser 105

qtc qtc tcg gtt ctg gaa ggt ggc gac ccg gtc gtc gtc gcc aac tcc Val Val Ser Val Leu Glu Gly Gly Asp Pro Val Val Val Ala Asn Ser 120

125

gag Glu	ggc Gly 130	tcc Ser	agg Arg	acc Thr	acc Thr	ccg Pro 135	tca Ser	att Ile	gtc Val	gcg Ala	ttc Phe 140	gcc Ala	cgc Arg	aac Asn	ggt Gly	432
gag Glu 145	gtg Val	ctg Leu	gtc Val	ggc Gly	cag Gln 150	ccc Pro	gcc Ala	aag Lys	aac Asn	cag Gln 155	gca Ala	gtg Val	acc Thr	aac Asn	gtc Val 160	480
				cgc Arg 165												528
ata Ile	gag Glu	att Ile	gac Asp 180	ggc Gly	aag Lys	aaa Lys	tac Tyr	acc Thr 185	gcg Ala	ccg Pro	gag Glu	atc Ile	agc Ser 190	gcc Ala	cgc Arg	576
				ctg Leu												624
				gtt Val												672
cgt Arg 225	cag Gln	gcc Ala	acc Thr	aag Lys	gac Asp 230	gcc Ala	ggc Gly	cag Gln	atc Ile	gcc Ala 235	ggc Gly	ctc Leu	aac Asn	gtg Val	ctg Leu 240	720
				gag Glu 245												768
				gag Glu												816
				tcc Ser												864
				ggt Gly												912
				tgg Trp												960
				gac Asp 325												1008
gag Glu	aag Lys	gca Ala	aag Lys 340	atc Ile	gag Glu	ctg Leu	agt Ser	tcg Ser 345	agt Ser	cag Gln	tcc Ser	acc Thr	tcg Ser 350	atc Ile	aac Asn	1056

ctg Leu	ccc Pro	tac Tyr 355	atc Ile	acc Thr	gtc Val	gac Asp	gcc Ala 360	gac Asp	aag Lys	aac Asn	ccg Pro	ttg Leu 365	ttc Phe	tta Leu	gac Asp	1104
		ctg Leu														1152
		act Thr														1200
tcg Ser	gtg Val	tcg Ser	gag Glu	atc Ile 405	gat Asp	cac His	gtt Val	gtg Val	ctc Leu 410	gtg V al	ggt Gly	ggt Gly	tcg Ser	acc Thr 415	cgg Arg	1248
		gcg Ala														1296
ecc Pro	aac Asn	aag Lys 435	ggc Gly	gtc Val	aac Asn	ccc Pro	gat Asp 440	gag Glu	gtt Val	gtc Val	gcg Ala	gtg Val 445	gga Gly	gcc Ala	gct Ala	1344
		gcc Ala														1392
		acc Thr														1440
		ctc Leu														1488
		acc Thr														1536
		999 Gly 515														1584
		ctg Leu														1632
		act Thr														1680
		aag Lys														1728

tcg ggc ctg tcc aag gaa gac att gac cgc atg atc aag gac gcc gaa Ser Gly Leu Ser Lys Glu Asp Ile Asp Arg Met Ile Lys Asp Ala Glu 580 585 590	1776
gcg cac gcc gag gag gat cgc aag cgt cgc gag gag gcc gat gtt cgt Ala His Ala Glu Glu Asp Arg Lys Arg Arg Glu Glu Ala Asp Val Arg 595 600 605	1824
aat caa gcc gag aca ttg gtc tac cag acg gag aag ttc gtc aaa gaa Asn Gln Ala Glu Thr Leu Val Tyr Gln Thr Glu Lys Phe Val Lys Glu 610 $$ 620 $$	1872
cag cgt gag gcc gag ggt ggt tcg aag gta cct gaa gac acg ctg aac Gln Arg Glu Ala Glu Gly Gly Ser Lys Val Pro Glu Asp Thr Leu Asn 625 630 635 640	1920
aag gtt gat gcc gcg gtg gcg gaa gcg aag gcg gca ctt ggc gga tcg Lys Val Asp Ala Ala Val Ala Glu Ala Lys Ala Ala Leu Gly Gly Ser 645 650 655	1968
gat att tog god atd aag tog gog atg gag aag otg ggd cag gag tog Asp Ile Ser Ala Ile Lys Ser Ala Met Glu Lys Leu Gly Gln Glu Ser 660 665 670	2016
cag gct ctg ggg caa gcg atc tac gaa gca gct cag gct gcg tca cag Gln Ala Leu Gly Gln Ala Ile Tyr Glu Ala Ala Gln Ala Ala Ser Gln 675 680 685	2064
gcc act ggc gct gcc cac ccc ggc tcg gct gat gaa agc a Ala Thr Gly Ala Ala His Pro Gly Ser Ala Asp Glu Ser 690 700	2104
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Pro Glu Thr Thr Asp Leu Tyr Cys Tyr Glu Gln Leu Asn Asp Ser Ser 20 25 30	
Glu Glu Glu Asp Glu Ile Asp Gly Pro Ala Gly Gln Ala Glu Pro Asp $35 \ \ 40 \ \ \ 45$	
Arg Ala His Tyr Asn Ile Val Thr Phe Cys Cys Lys Cys Asp Ser Thr $50 \\ 0 \\ 60$	
Leu Arg Leu Cys Val Gln Ser Thr His Val Asp Ile Arg Thr Leu Glu 65 70 75 80	

- Asp Leu Leu Met Gly Thr Leu Gly Ile Val Cys Pro Ile Cys Ser Gln 85 90 95 Gly Ser Met Ala Arg Ala Val Gly Ile Asp Leu Gly Thr Thr Asn Ser
- 100 105 110

 Val Val Ser Val Leu Glu Gly Gly Asp Pro Val Val Val Ala Asn Ser
 115 120 125
- Glu Gly Ser Arg Thr Thr Pro Ser Ile Val Ala Phe Ala Arg Asn Gly
- Glu Val Leu Val Gly Gln Pro Ala Lys Asn Gln Ala Val Thr Asn Val 145 150 155 160
- Asp Arg Thr Val Arg Ser Val Lys Arg His Met Gly Ser Asp Trp Ser
- Ile Glu Ile Asp Gly Lys Lys Tyr Thr Ala Pro Glu Ile Ser Ala Arg 180 185 190
- Ile Leu Met Lys Leu Lys Arg Asp Ala Glu Ala Tyr Leu Gly Glu Asp 195 200 205
- Arg Gln Ala Thr Lys Asp Ala Gly Gln Ile Ala Gly Leu Asn Val Leu 225 230235235
- Arg Ile Val Asn Glu Pro Thr Ala Ala Ala Leu Ala Tyr Gly Leu Asp 245 250 255
- Lys Gly Glu Lys Glu Gln Arg Ile Leu Val Phe Asp Leu Gly Gly Gly 260 \$265\$
- Thr Phe Asp Val Ser Leu Leu Glu Ile Gly Glu Gly Val Val Glu Val 275 280 285
- Arg Ala Thr Ser Gly Asp Asn His Leu Gly Gly Asp Asp Trp Asp Gln 290 \$295\$
- Arg Val Val Asp Trp Leu Val Asp Lys Phe Lys Gly Thr Ser Gly Ile 305 310 315 320
- Asp Leu Thr Lys Asp Lys Met Ala Met Gln Arg Leu Arg Glu Ala Ala 325 330 335
- Glu Lys Ala Lys Ile Glu Leu Ser Ser Ser Gln Ser Thr Ser Ile Asn $340 \hspace{1cm} 345 \hspace{1cm} 350$
- Leu Pro Tyr Ile Thr Val Asp Ala Asp Lys Asn Pro Leu Phe Leu Asp 355 360 365
- Glu Gln Leu Thr Arg Ala Glu Phe Gln Arg Ile Thr Gln Asp Leu Leu 370 375 380

Asp Arg Thr Arg Lys Pro Phe Gln Ser Val lle Ala Asp Thr Gly Ile 400

Ser Val Ser Glu Ile Asp His Val Val Leu Val Gly Gly Ser Thr Arg 415

Met Pro Ala Val Thr Asp Leu Val Lys Glu Leu Thr Gly Gly Lys Glu 425

Pro Asn Lys Gly Val Asn Pro Asp Glu Val Val Val Ala Val Gly Ala Ala Ala 435

Leu Gln Ala Gly Val Leu Lys Gly Glu Val Lys Asp Val Leu Leu Leu 450

Asp Val Thr Pro Leu Ser Leu Gly Ile Glu Thr Lys Gly Gly Val Met 465

Thr Arg Leu Ile Glu Arg Asn Thr Thr Ile Pro Thr Lys Arg Ser Glu 485

Thr Phe Thr Thr Ala Asp Asp Asn Gln Pro Ser Val Gln Ile Gln Val 500

Tyr Gln Gly Glu Arg Glu Ile Ala Ala His Asn Lys Leu Leu Gly Ser 525

Phe Glu Leu Thr Gly Ile Pro Pro Ala Pro Arg Gly Ile Pro Gln Ile 530

Glu Val Thr Phe Asp Ile Asp Ala Asn Gly Ile Val His Val Thr Ala 560

Glu Val Thr Phe Asp Ile Asp Ala Asn Gly Ile Val His Val Thr Ala 560

545 550 555 560 Lys Asp Lys Gly Thr Gly Lys Glu Asn Thr Ile Arg Ile Glu Glu Gly 565 570 575

Ser Gly Leu Ser Lys Glu Asp Ile Asp Arg Met Ile Lys Asp Ala Glu 580 585

Ala His Ala Glu Glu Asp Arg Lys Arg Glu Glu Ala Asp Val Arg
595 600 605

Asn Gln Ala Glu Thr Leu Val Tyr Gln Thr Glu Lys Phe Val Lys Glu

610 615 620
Gln Arg Glu Ala Glu Gly Gly Ser Lys Val Pro Glu Asp Thr Leu Asn

625 630 635 640 Lys Val Asp Ala Ala Val Ala Glu Ala Lys Ala Ala Leu Gly Gly Ser

645 650 655

Asp Ile Ser Ala Ile Lys Ser Ala Met Glu Lys Leu Gly Gln Glu Ser

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<213> Artificial Sequence

<223> Description of Artificial Sequence: Synthetic vector

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taggatggca agatcctggt atcggtctgc gattccgact cgtccaacat 1740 caatacaacc tattaatttc ccctcgtcaa aaataaggtt atcaagtgag aaatcaccat 1800 gagtgacgac tgaatccggt gagaatggca aaagcttatg catttctttc cagacttgtt 1860 caacaggeca gecattaege tegteateaa aateaetege ateaaceaaa cegttattea 1920 ttcgtgattg cgcctgagcg agacgaaata cgcgatcgct gttaaaagga caattacaaa 1980 caqqaatcga atgcaaccgg cgcaggaaca ctgccagcgc atcaacaata ttttcacctg 2040 aatcaqqata ttcttctaat acctggaatg ctgttttccc ggggatcgca gtggtgagta 2100 accatgcatc atcaggagta cggataaaat gcttgatggt cggaagaggc ataaattccg 2160 tragcragtt tagtotgacc atotratotg taacatratt ggraacgota cotttgccat 2220 gtttcagaaa caactetgge gcateggget teccatacaa tegatagatt gtegeacetg 2280 attgcccgac attatcgcga gcccatttat acccatataa atcagcatcc atgttggaat 2340 ttaategegg cetegageaa gaegttteee gttgaatatg geteataaca cecettgtat 2400 tactgtttat gtaagcagac agttttattg ttcatgatga tatattttta tcttgtgcaa 2460 tgtaacatca gagattttga gacacaacgt ggctttcccc cccccccat tattgaagca 2520 tttatcaggg 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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Wu, Tzyy-Choou et al.

Application No: 10/555,669

International Filing Date: May 5, 2004

For: ANTI-CANCER DNA VACCINE

EMPLOYING PLASMIDS ENCODING SIGNAL SEQUENCE, MUTANT ONCO-PROTEIN ANTIGEN, AND HEAT

SHOCK PROTEIN

Art Unit: To be Determined

Confirmation No.: 9879

Examiner: To be Determined

Docket No. JHV-050.01

CERTIFICATE OF FIRST CLASS MAILING

I hereby certify that the foregoing documents are being deposited with the United States Postal Service as First Class Mail, in an envelope addressed to Mail Stop PCT (DO/EO/US), Commissioner fax, Patents, P.O. Box 1450, Alexandria VA 22313-1450, on this date of March 19, 2007.

PRELIMINARY AMENDMENT

Mail Stop PCT (DO/EO/US) Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir/Madam:

Prior to substantive examination of the above-referenced patent application, please amend the application as follows:

Amendments to the specification begin on page 2 of this paper.

Remarks begin on page 3 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph beginning on page 8, line 13 with the following amended paragraph:

Figure 5A is a schematic diagram of the pNGVL4a-Sig/E7 (detox) /HSP70 plasmid vector used for anti-tumor vaccination. Indicated are various inserts and p Fig. 5B discloses SEQ ID NOs: 17-20, respectively, in order of appearance.

Please replace the paragraph beginning on page 34, line 6 with the following amended paragraph:

A portion of SEQ ID NO: 13 above vector showing by annotation annotated with the Sig, E7 (detox) and HSP-70 regions is shown below (nucleotides 3951-6350 of SEQ ID NO: 13). The vector sequence is in lower case; the signal peptide (Sig) is bold italic and annotated over the lines. The E7 (detox) sequence is upper case underscored (and annotated over the lines). The HSP70 sequence is italicized and underscored[[.]] (not bolded) and is also annotated over the lines.

REMARKS

The foregoing amendments have been made to correct typographical errors and to insert the required SEQ ID NO identifiers associated with various listed sequences. No new matter has been added.

CONCLUSION

Applicants respectfully request entry of the present Preliminary Amendment. Early and favorable consideration of the application is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at (617) 832-1000. The Commissioner is hereby authorized to charge any necessary fees to our **Deposit Order Account** No. 06-1448, reference JHV-050.01.

Respectfully submitted, FOLEY HOAG

Dated: March 19, 2007 Customer Number 25181 Patent Group Foley Hoag LLP 155 Seaport Blvd. Boston, MA 02210-2600 Tel: (617) 832-1000 FAX: (617) 832-7000

Janann Y. Ali, Ph.D. Reg. No. 54,958 Agent for Applicant

DECLARAT		FOR UTILITY OR DE ION DATA SHEET (3		ATION USING AN					
Title of Invention		VACCINE EMPLOYING F		DING SIGNAL SEQUENCE, TEIN					
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	x as amende	d on11/	07/2005	(if applicable);					
I/we believe that I/we sought;	am/are the original and fir	st inventor(s) of the subject	matter which is clair	med and for which a patent is					
I/we have réviewed ar amendment specifical		s of the above-identified app	lication, including th	e claims, as amended by any					
material to patentabilit	ty as defined in 37 CFR 1 ween the filing date of the	.56, including for continuation	n-in-part application	rmation known to me/us to be ns, material information which nternational filing date of the					
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may contribute to ide card numbers (other required by the USPT submitted to the USP before submitting ther the public after public in the application) or it to the public if the app credit card authorizal therefore are not publi	Petitioner/applicant is castioned to avoid submitting personal information in documents field in a planet application that any contribute to identity thet. Personal information such as social security numbers, so has account numbers, or credit card numbers (other than a check or credit card authorization from PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioner/applicants should consider reducing such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patient applicant or available to the public after publication of the application (infless a non-publication request in compliance with 37 CFR 1.215(a) is made in the application or issuance of a patient. Furthermore, the record from a better desired such personal information from the documents of the publication of the application of the applic								
believed to be true, an	nd further that these stater or imprisonment, or both	ments were made with the ki	nowledge that willful	on information and belief are I false statements and the like e validity of the application or					
FULL NAME OF IN	VENTOR(S)								
Inventor one: T:	zyy-Choou Wu								
Signature:	Vm Zom.	Long Citize	n of:	_ A					
Inventor two: C	hien-Fu Hung								
Signature:(cf U	Citize	n of:	niwan					
Inventor three:	•								
Signature:		Citize	n of:	*					
Inventor four:									
Signature:		Citize	n of:						
Additional inven	tore or a legal representat	ive are being named on	additional	form(e) attached hereto					

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Application Number | 10/1555,669-Conf. #9870.

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POWER OF AT	TORNEY	Title								
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INDICATION	FORM				AT SHOCK PROTEIN					
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Title and Company Inventor										
NOTE. Signatures of all the invento	rs or assignees of record o	f the entir	e interest or their r	epresentative	s) are required. Submit multiple					
forms if more than one signature is	required, see below*.									
X *Total of 2	forms are submitte	ed.								

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Wu, Tzyy-Choou et al.

Application No: 10/555,669

International Filing Date: May 5, 2004

For: ANTI-CANCER DNA VACCINE
EMPLOYING PLASMIDS ENCODING
SIGNAL SEQUENCE, MUTANT ONCOPROTEIN ANTIGEN, AND HEAT
SHOCK PROTEIN

Art Unit: To be Determined

Confirmation No.: 9879

Examiner: To be Determined

Docket No. JHV-050.01

CERTIFICATE OF FIRST CLASS MAILING

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NOTIFICATION OF CHANGE OF ATTORNEY DOCKET NUMBER

Mail Stop PCT (DO/EO/US) Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir

The Attorney Docket Number of the above-identified patent application has changed. Please take notice that the *correct* Attorney Docket Number for this application should now be as follows:

JHV-050.01

Please reference JHV-050.01 on all future correspondence to the attorney of record.

Respectfully Submitted,

Date: March 19, 2007

Customer No: 25181
Patent Group
Foley Hoag LLP
155 Seaport Blvd.
Boston, MA 02210-2600

Janann 7. Ali, Ph.D. Reg. No. 54,958 Agent for Applicants Tel. (617) 832-1000 Fax. (617) 832-7000